Nos. 22-2217, 23-1021

United States Court of Appeals
for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,

Plaintiff-Cross-Appellant,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Delaware, No. 20-755, Judge Richard Andrews

APPELLANT LIQUIDIA TECHNOLOGIES, INC. COMBINED PETITION FOR PANEL AND EN BANC REHEARING

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-2217, 23-1021

Short Case Caption United Therapeutics Corporation v. Liquidia Technologies, Inc.

Filing Party/Entity Liquidia Technologies, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 08/23/2023

Signature: /s/ Sanya Sukduang

Name: Sanya Sukduang

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Liquidia Technologies, Inc.		Liquidia Corporation

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Sanya Sukduang, Cooley LLP	Jonathan Davies, Cooley LLP	Ivor R. Elrifi, Cooley LLP
Erik B. Milch, Cooley LLP	Deepa Kannappan, Cooley LLP	

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

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☑ None/Not Applicable ☐ Additional pages attached

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RULE 35(B)(2) AND 40(A)(5) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decision of the Supreme Court of the United States and this Court:

Commil USA, LLC v. Cisco Systems, Inc., 575 U.S. 632, 644 (2015)

Based on my professional judgment, I also believe this appeal requires an answer to the following precedent-setting question of exceptional importance:

1. Whether an *Inter Partes* Review Final Written Decision from the Patent Trial and Appeal Board rendering unpatentable all issued claims should be considered in assessing an accused infringer's subjective intent to induce infringement and whether such a decision is sufficient to negate liability for induced infringement under 35 U.S.C. § 271(b).

Dated: August 23, 2023

/s/ Sanya Sukduang

Sanya Sukduang
Cooley LLP

Counsel for Defendant-Appellant Liquidia Technologies, Inc

REASONS FOR GRANTING THE PETITON

In *Commil*, the Supreme Court determined that a mere "good-faith belief in invalidity" is insufficient to negate liability for induced infringement, but separately identified several "proper ways" an accused infringer can move beyond a good-faith belief and obtain actual knowledge of patent invalidity. 575 U.S. at 645. One such "proper way" is through an "*inter partes* review at the [Board] and receiv[ing] a decision as to validity within 12 to 18 months." *Id.* (citing 35 U.S.C. § 316). Upon receiving that ruling, the Supreme Court made clear that an accused infringer "will be immune from liability." *Id.*

Rather than follow this clear guidance from the Supreme Court, the Panel instead declared a new rule imposing a different time point to negate the intent to induce infringement–***after*** affirmance from this Court such that collateral estoppel attaches. ECF No. 61 ("Opinion"), 19. The Supreme Court said nothing in *Commil* that would lead to the conclusion that collateral estoppel would be needed to defeat the requisite scienter and immunize an accused infringer from liability. To the contrary, the Supreme Court, citing 35 U.S.C. § 316, made clear that only a Final Written Decision ("FWD"), obtained within 12 to 18 months, was necessary. Because the Panel's new rule requiring collateral estoppel is inconsistent with the timing set forth in the Supreme Court's *Commil* decision, rehearing should be granted.

Additionally, in its discussion of *Commil*, the Panel referenced that unpatentability is only confirmed once the Director of the United States Patent and Trademark Office issues a certificate under 35 U.S.C. § 318 cancelling claims. Opinion, 19. Thus, although the Panel correctly cited *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018), for the proposition that a panel affirmance of an *Inter Partes* Review ("IPR") has immediate collateral estoppel effect as to invalidity, the Panel has created ambiguity as to when, even under its holding, a decision in an IPR proceeding will negate intent for purposes of determining induced infringement liability – whether it occurs when collateral estoppel attaches or only at claim cancellation. Accordingly, rehearing should be granted to remove such ambiguity and make clear that an IPR FWD will negate the requisite intent for induced infringement, at the latest, when collateral estoppel attaches.

SUMMARY OF THE APPEALED DISTRICT COURT DECISION

Co-pending with the district court's adjudication of infringement and validity of United Therapeutics Corporation's ("UTC") U.S. Patent No. 10,716,793 (the "'793 patent") was Liquidia's IPR of the '793 patent. The district court correctly noted that on July 19, 2022, prior to the district court's August 31, 2022 Opinion, the PTAB issued a FWD "invalidating all claims of the '793 patent as obvious." Appx00055; *see also*, Appx31148-31196. Based on the PTAB's '793 FWD,

Liquidia argued to the district court that pursuant to *Commil*, it cannot be liable for induced infringement of the '793 patent because Liquidia does not have the subjective intent to induce another's infringement of a patent deemed, under proper Patent Office procedures, invalid. Appx31145; Appx31197-31201. In assessing Liquidia's liability for induced infringement, the district court pointed to Liquidia's 2021 proposed label as sufficient evidence establishing Liquidia's intent to induce infringement. Appx00055-00056; Appx29540-29541. The district court also recited portions of *Commil* but stated that "[t]he Supreme Court never stated, however, that a PTAB decision invalidating patent claims in an IPR will preclude liability before it becomes final and nonappealable." Appx00056 (citing *Commil*, 575 U.S. at 644-45). As such, the district court, without addressing the '793 FWD's impact on Liquidia's ***subjective intent***, determined that *Commil* does not compel the court "to treat the '793 patent as invalid for purposes of assessing Liquidia's induced infringement." *Id.* The district court went on to state that an IPR decision does not have collateral estoppel effect until affirmed by the Federal Circuit---or the parties waive their rights to appeal. *Id.* The district court also noted that the '793 patent claims are not cancelled until the PTO Director issues a certificate, pursuant to 35 U.S.C. § 318, canceling the claims. *Id.* The district court concluded that the "PTAB's decision—which is not yet final—has no impact on my finding of induced infringement." Appx00057.

SUMMARY OF THE FEDERAL CIRCUIT PANEL DECISION

Despite extensive briefing before the Panel on the impact of the PTAB's '793 FWD in view of *Commil*, the Panel summarily determined, as an issue of first impression, that an IPR FWD "does not negate an intent to infringe that is otherwise supported by the evidence." Opinion, 19; Blue Br., 18-19, 46-54; Red Br., 24-31; Yellow Br., 15-19. In doing so the Panel, like the district court, did not (1) account for Liquidia's ***subjective intent*** to induce infringement after issuance of the '793 FWD; (2) address *Commil's* reference to the importance of an IPR FWD within "12 to 18 months"; or (3) account for *Commil's* citation to 35 U.S.C. § 316. Opinion, 18-19. Instead, relying solely on Liquidia's proposed 2021 label, prepared before the PTAB's July 2022 '793 IPR FWD (Appx29540), the Panel determined the district court did not commit error in finding induced infringement. Opinion, 18.

To support its conclusion, the Panel cited *XY* for the proposition that "an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights." *Id*., 19. The Panel also stated that only the Director, upon issuance of a certificate under 35 U.S.C. § 318, can finally cancel claims that were previously determined to be unpatentable. *Id*.

ARGUMENT

I. IN ACCORDANCE WITH THE SUPREME COURT'S DECISION IN *COMMIL*, THE PTAB'S '793 FWD IMMEDIATELY NEGATES LIQUIDIA'S LIABILITY FOR INDUCED INFRINGEMENT

A. Subjective Intent is Required to Establish Induced Infringement Liability

An essential element of induced infringement under 35 U.S.C. §271(b) is intent, and as explained by this Court, relying on Supreme Court precedent, "[t]he intent element requires 'knowledge that the induced acts constitute patent infringement,' which can be established by a proper finding of 'willful blindness.'" *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1286 (Fed. Cir. 2020) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. 754, 766-71 (2011)); *see also*, *Commil*, 575 U.S. at 642 (induced infringement "requires proof the defendant knew the acts were infringing. And the [Supreme] Court's opinion was clear in rejecting any lesser mental state as the standard."). Consequently, "[t]he intent standard for inducement, therefore, 'focuses on, and can be met by proof of, the defendant's subjective state of mind, whether actual knowledge or the subjective beliefs (coupled with action to avoid learning more) that characterizes willful blindness.'" *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F.4th 1109, 1118 (Fed. Cir. 2022) (quoting *TechSec*, 978 F.3d at 1286). Accordingly, any determination on induced infringement requires a finding that the accused infringer has the subjective state of mind to induce another to infringe.

B. *Commil* Only Requires an IPR FWD to Negate Induced Infringement Liability

The Supreme Court in *Commil* was faced with the questions of "whether ***knowledge of***, ***or belief in***, a patent's validity is required for induced infringement under § 271(b)." 575 U.S. at 639 (emphasis added). The Supreme Court answered this question by holding that a mere ***good faith belief*** of patent invalidity is not a defense to induced infringement. *Id*. at 642 ("[B]elief regarding validity cannot negate the scienter required under § 271(b)."). However, in contrasting a good faith belief with actual "knowledge of" invalidity, the Supreme Court stated: "[t]o be sure, if at the end of the day, an act that would have been an . . . inducement to infringe pertains to a patent that is ***shown to be invalid***, there is no patent to be infringed." *Id.* at 641, 644 (emphasis added). Going further, the Supreme Court confirmed that the subjective intent element of induced infringement is negated, and liability eliminated, if "[a]n accused infringer can . . . prove that patent in suit is invalid[,]" because "***if the patent is indeed invalid***, ***and shown to be so under proper procedures, there is no liability***." *Id.* at 644 (emphasis added).

The *Commil* decision determined that a mere good faith belief in patent invalidity was insufficient to negate induced infringement liability. The Supreme Court, however, went on to explain that "accused inducers who believe a patent is invalid have various ***proper ways to obtain a ruling to that effect***." *Id.* at 645 (emphasis added). As listed by the Supreme Court, [t]he "proper ways" to obtain a

"ruling" of invalidity include a declaratory judgment action in a district court seeking to declare the patent invalid; *ex parte* reexamination before the PTO; raising an affirmative defense of invalidity at the district court; or seeking "*inter partes* review at the [Board] and receiv[ing] a decision as to validity within 12 to 18 months. *See* [35 U.S.C.] § 316." *Id*. Under any of these "proper ways," an accused infringer can obtain a "ruling" of invalidity, and thus "actual knowledge" of invalidity, immediately negating liability for induced infringement.

Germane here is the Supreme Court's discussion of IPR proceedings. In particular, in referencing a "decision as to validity within 12 to 18 months[,]" and specifically citing 35 U.S.C. § 316, the Supreme Court made clear that only an initial FWD or "ruling" was required—not a later decision creating finality with accompanying collateral estoppel effect. *Id.* at 645.

Section 316 statutorily requires the Board to issue its IPR FWD within 12 to 18 months:

> [T]he final determination in an inter partes review [must] be issued ***not later than 1 year*** [12 months] after the date on which the Director notices the institution of a review under this chapter, ***except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months*** [18 months], and may adjust the time periods in this paragraph in the case of joinder under section 315(c)[.]

35 U.S.C. § 316(a)(11) (emphases added). The *Commil* Court stated plainly that an IPR FWD is the type of "ruling" an accused infringer can point to in order to negate the scienter element of induced infringement.

Further establishing that an IPR FWD, alone, is sufficient to immediately negate induced infringement liability is what the Supreme Court ***did not*** rely on. For instance, *Commil* ***did not*** reference issuance of a Director's certificate cancelling claims under 35 U.S.C. § 318(b). Section 318 is not foreign to the Supreme Court, which has cited it in several cases, including *U.S. v. Arthrex*, *Inc.*, 141 S. Ct. 1970, 1978 (2021). In *Arthrex*, 35 U.S.C. § 316 was also cited (*id.* at 1977), demonstrating that *Commil's* reliance on § 316, and not § 318, was purposeful. Further, *Commil* discussed obtaining a "ruling" of invalidity, of which an IPR FWD is one. *Commil* never mentioned, let alone required, affirmance or finality of a ruling or cancellation of patent claims in order to achieve the result of negating scienter or liability.

C. This Court Should Grant En Banc Review Because the Panel Decision's New Rule Governing Induced Infringement Liability Conflicts with *Commil*

By announcing a new rule that liability for induced infringement cannot be negated by an IPR FWD invalidating all asserted claims, the Panel's decision is in direct conflict with Supreme Court precedent. En banc review is warranted to correct this legal error.

Collateral estoppel based on an affirmance of an IPR FWD invalidating all asserted claims is a validity issue—not an infringement issue; it prevents UTC from re-litigating the validity of the '793 patent. *Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am*., *Inc.*, 924 F.3d 1243, 1250-51 (Fed. Cir. 2019). The question before the Panel was not whether the '793 patent was invalid, but instead the impact of the '793 FWD on Liquidia's ***subjective intent*** to induce infringement. The Panel conflated the subjective intent question with the question of validity by requiring collateral estoppel before an IPR FWD has any effect, thereby converting a question of infringement into a question of validity. *Commil* made clear this was not the proper inquiry. 575 U.S. at 643 ("[I]nfringement and invalidity are separate matters under patent law.") In other words, the Panel's new rule improperly collapses the issue of intent to induce infringement into the analysis of validity, holding that an accused infringer's subjective state of mind cannot change until an IPR FWD is affirmed on appeal (*i.e.*, when validity has been finally determined by collateral estoppel). This timing is legally incorrect under *Commil*.

By stating that an IPR "ruling" obtained with 12 to 18 months was a "proper way" for accused infringers to obtain a successful outcome immunizing them from liability, the Supreme Court set this timing at 12 to 18 months, not significantly later when collateral estoppel applies. *Id.* at 645. In fact, the Supreme Court equated IPR FWD's obtained within 12 to 18 months with (unaffirmed) district court decisions

on invalidity obtained at trial—both "proper ways" allowing an accused infringer to obtain actual knowledge of invalidity and immunity from induced infringement liability while also permitting a patent owner with a full and fair opportunity to be heard. *Id.*

The Supreme Court's determination that an IPR FWD is sufficient to negate liability makes sense when assessing induced infringement because that decision, obtained 12 to 18 months after an IPR petition is filed, directly and immediately implicates the subjective state of mind of an accused inducer, such as Liquidia. A government entity, in fact the very entity in charge of issuing patents, is telling the world that the patent is invalid—a company in the marketplace should be able to rely on that government entity's determination. To be clear, there can be no dispute that the '793 patent has been invalidated, and Judge Lourie acknowledged as much during oral argument. *See* Oral Arg. at 14:00-14:13, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-2217_05032023.mp3. Thus, knowledge of invalidity, as opposed to a mere good faith belief, has been obtained. And this knowledge alone, as opposed to affirmance on appeal to this Court, is immediately sufficient under *Commil* to negate Liquidia's liability for induced infringement and keeps separate the infringement and validity inquiries.

Further, by referencing claim cancellation under 35 U.S.C. § 318 in the context of assessing intent to induce infringement, the Panel not only completely

disregarded the statutory section actually relied on in *Commil*—§ 316—but created ambiguity as to whether both collateral estoppel ***and*** claim cancellation under § 318 is required to negate for the intent to induce infringement. There is simply no factual or legal basis to deviate from the timing set forth in *Commil* and require claim cancellation as an additional prerequisite to negate the intent to induce infringement.

The Panel's decision, referencing the cancellation of claims under 35 U.S.C. § 318, opens the door for patentees to argue that, although an affirmed IPR FWD on invalidity has immediate preclusive effect on the issue of validity, it has no preclusive effect for assessing the intent to induce infringement until the claims are cancelled. In sum, the Panel's decision could be interpreted to require more to negate the intent to induce infringement of a patent than is needed for an affirmed invalidity decision to have preclusive effect as to the validity of the very same patent in a co-pending or subsequent proceeding. To the extent the Court believes the Panel's decision requires both collateral estoppel and claim cancellation under § 318 before liability for intent to induced infringement can be negated, then en banc review is needed to address the degree to which this Court's decision in *XY* has been overruled. *See Deckers Corp. v. U.S.*, 752 F.3d 949, 964 (Fed. Cir. 2014) (explaining a panel may be overruled only by an intervening Supreme Court or en banc decision); Fed. Cir. R. 35(a)(1).

Finally, giving immediate effect to an IPR FWD in the context of induced infringement is also consistent with the policy behind Congressional enactment of IPR proceedings, which is to prevent invalid patents from having an adverse impact on the public. Here, despite the fact that the PTAB's '793 IPR FWD invalidated all claims issued a month before the district court's decision, the district court nonetheless issued a Hatch-Waxman injunction under 35 U.S.C. § 271(e)(4), based solely on the '793 patent, preventing the FDA from granting final approval to Liquidia's NDA. Appx00073; Appx00076. As a result, pulmonary arterial hypertension patients have been deprived of Liquidia's novel dry powder therapeutic treatment. Appx00021-00022; Appellee's Motion to Expedite Briefing and Oral Argument at *1-2, *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2023-1805 (Fed. Cir. May 22, 2023), ECF No. 10. A patent deemed invalid by the PTAB in an IPR FWD should not be the basis for an injunction.

CONCLUSION

The Panel's newly enacted rule is squarely in conflict with the Supreme Court's decision in *Commil* and en banc rehearing is required. And because, under *Commil*, the PTAB's '793 IPR FWD negates Liquidia's intent to induce infringement, the en banc court should reverse the district court's decision.

Additionally, to the extent the Court believes the Panel's decision requires ***both*** collateral estoppel and claim cancellation under § 318 before intent to induce

infringement can be negated, Panel rehearing and/or en banc review is needed to rectify this error.

Dated: August 23, 2023

Respectfully submitted,

/s/ Sanya Sukduang

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Counsel for Defendant-Appellant Liquidia Technologies, Inc.

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 23rd day of August, 2023, I caused this Petition for Panel and En Banc Rehearing to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the all registered CM/ECF users.

/s/ Sanya Sukduang
Sanya Sukduang
Cooley LLP

Counsel for Defendant-Appellant
Liquidia Technologies, Inc

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the type-volume limitations of the Federal Rules of Appellate Procedure and Federal Circuit Rules, has been prepared using a proportionally-spaced typeface, and includes 2,992 words.

Dated: August 23, 2023

/s/ Sanya Sukduang

Sanya Sukduang
Cooley LLP

Counsel for Defendant-Appellant Liquidia Technologies, Inc

ADDENDUM

United States Court of Appeals for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,
Plaintiff-Cross-Appellant

v.

LIQUIDIA TECHNOLOGIES, INC.,
Defendant-Appellant

2022-2217, 2023-1021

Appeals from the United States District Court for the District of Delaware in No. 1:20-cv-00755-RGA-JLH, Judge Richard G. Andrews.

Decided: July 24, 2023

SANYA SUKDUANG, Cooley LLP, Washington, DC, argued for defendant-appellant. Also represented by JONATHAN DAVIES; DEEPA KANNAPPAN, Palo Alto, CA; ERIK BENTON MILCH, Reston, VA.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for plaintiff-cross-appellant. Also represented by WILLIAM COVINGTON JACKSON, JAIME SANTOS, ROHINIYURIE TASHIMA, JENNY J. ZHANG; GERARD JUSTIN CEDRONE, Boston, MA; ADAM WILLIAM BURROWBRIDGE. McDermott Will & Emery, LLP, Washington, DC; DOUGLAS H. CARSTEN, ARTHUR PAUL DYKHUIS, Irvine, CA;

SHAUN R. SNADER, United Therapeutics Corporation, Washington, DC.

Before LOURIE, DYK, and STOLL, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Liquidia Technologies, Inc. ("Liquidia") appeals from a decision of the United States District Court for the District of Delaware holding that (1) claims 1, 4, and 6–8 of U.S. Patent 10,716,793 ("the '793 patent") are not invalid and are infringed by Liquidia and (2) claims 1–3 of U.S. Patent 9,593,066 ("the '066 patent") are invalid as anticipated, but are otherwise infringed by Liquidia. United Therapeutics Corporation ("United Therapeutics") cross-appeals from the court's decision holding that (1) claims 1–3, 6, and 9 of the '066 patent are invalid as anticipated and (2) claims 6, 8, and 9 of the '066 patent are not infringed by Liquidia. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436 (D. Del. 2022) ("*Decision*"). For the reasons provided below, we affirm.

BACKGROUND

United Therapeutics holds New Drug Application ("NDA") No. 022387 for Tyvaso®, an inhaled solution formulation of treprostinil approved for the treatment of pulmonary hypertension ("PH"). Pulmonary hypertension is a potentially life-threatening condition characterized generally by abnormally high blood pressure in the lungs. For many patients, treprostinil is used in treating pulmonary hypertension because it is a vasodilator that reduces vasoconstriction in the pulmonary vasculature, thereby decreasing blood pressure.

Experts consider that there are five subgroups of pulmonary hypertension: Group 1, pulmonary arterial hypertension ("PAH"); Group 2, pulmonary venous hypertension, *i.e.*, pulmonary hypertension related to left-heart disease;

Group 3, pulmonary hypertension associated with disorders damaging the lungs; Group 4, pulmonary hypertension caused by chronic thrombotic or embolic disease, including chronic blood clots in the lungs; and Group 5, a miscellaneous category for conditions that do not fit well into the other four subgroups. Groups 1, 3, 4, and 5 are caused by conditions affecting the pulmonary arteries or precapillary vessels of the lungs ("precapillary PH"), while Group 2 typically develops as a result of a cardiac-based etiology ("postcapillary PH"). Due to differing etiologies, each group may require group-specific treatment.

United Therapeutics owns the '793 and '066 patents, which are generally directed to methods of treating pulmonary hypertension and to pharmaceutical compositions comprising treprostinil. The '793 and '066 patents are listed in the FDA's Orange Book for Tyvaso.

Liquidia filed NDA No. 213005 for Yutrepia™ under § 505(b)(2) of the Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 355(b)(2)). [1] Yutrepia is a dry powder

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[1] Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman amendments to the Food, Drug, and Cosmetic Act), an NDA filed under § 505(b)(2) contains full reports of investigations of safety and effectiveness, where at least some of the information used for approval comes from studies that were not conducted for or by the applicant. Such an NDA is one of two abbreviated approval pathways introduced by the Hatch-Waxman amendments, the other being an abbreviated new drug application ("ANDA") filed under § 505(j) (codified at 21 U.S.C. § 355(j)). 35 U.S.C. § 271(e)(2), the statutory provision delineating acts of infringement, covers both types of applications: "It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in

inhalation formulation of treprostinil but is not a generic version of any currently marketed drug. Pursuant to § 505(c)(3)(C) (codified at 21 U.S.C. § 355(c)(3)(C)), United Therapeutics sued Liquidia within 45 days of receipt of notice of Liquidia's NDA in the United States District Court for the District of Delaware alleging infringement of the '066 patent. J.A. 171, 190. In addition, after Liquidia filed its NDA, United Therapeutics filed another patent application that eventually issued as the '793 patent, which was subsequently added to the district court litigation. J.A. 208.

In parallel, Liquidia filed a petition for *inter partes* review ("IPR") of the '793 patent, alleging that all claims would have been unpatentable as obvious over prior art at the time of the invention. On July 19, 2022, the Board issued a Final Written Decision finding all claims of the '793 patent unpatentable as obvious. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. IPR2021-00406, 2022 WL 2820717 (P.T.A.B. July 19, 2022). United Therapeutics filed a Request for Rehearing, challenging whether various asserted references qualified as prior art. J.A. 36648. In its Rehearing Decision, the Board found that the references were prior art, again holding the claims of the '793 patent unpatentable as obvious. United Therapeutics filed a Notice of Appeal in that case on April 26, 2023. Liquidia filed a motion for expedited appeal, which has been denied. The appeal is currently pending in this court.

I. The '793 Patent

The '793 patent is directed to a method of treating pulmonary hypertension comprising inhalation of treprostinil. Asserted claim 1 of the '793 patent is the only independent claim and reads as follows:

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section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]"

> 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

'793 patent at col. 18 ll. 23–31.

The additional asserted dependent claims include limitations directed to dry powder inhalers (claim 4), powder formulations (claim 6), powder formulations comprising particles less than 5 micrometers in diameter (claim 7), and formulations containing no metacresol (claim 8). *See id.* col. 18 ll. 36–37, 40–45.

In the district court, United Therapeutics argued that, although Liquidia's proposed product had not yet been marketed, when marketed, it (1) would directly infringe claims 1, 4, and 6–8 of the '793 patent and (2) would also induce infringement of those claims. Liquidia responded that the asserted claims were invalid as lacking adequate enablement and written description under 35 U.S.C. § 112.

The district court found that United Therapeutics showed that a single administration of treprostinil, as required by claim 1, improves a patient's hemodynamics, establishing that administration of Liquidia's Yutrepia, comprising treprostinil, at the claimed doses will also improve a patient's hemodynamics. The court concluded that United Therapeutics thus proved by a preponderance of the evidence that the administration of Yutrepia will directly infringe claims 1, 4, and 6–8 of the '793 patent.

The district court also concluded that Liquidia's argument that it lacked specific intent to induce infringement lacked merit. Liquidia argued that, because the Yutrepia label does not encourage administration of a therapeutically effective single event dose, it does not induce infringement. The court noted that the label does not need to provide hemodynamic data to constitute inducement of infringement; instead, it merely needs to instruct doctors and patients to administer a therapeutically effective single event dose. The court found that the label's instructions will inevitably lead to the administration of a therapeutically effective single event dose. The court thus concluded that United Therapeutics proved by a preponderance of the evidence that Liquidia will induce infringement of claims 1, 4, and 6–8 of the '793 patent.

The district court further found that the asserted claims were not invalid for lack of enablement or written description. First, the court construed "treating pulmonary hypertension" as encompassing all five groups of pulmonary hypertension, noting that the specification of the '793 patent expressly includes all five groups when describing "pulmonary hypertension." Second, the court found that a skilled artisan would not need to engage in undue experimentation to practice the full scope of the claimed treatment of pulmonary hypertension, despite potential safety concerns in treating Group 2 PH patients, and that the claims did not require safety and efficacy. Third, the court found that the claims were not invalid for lack of written description, finding that a skilled artisan would, based on the specification, understand that treprostinil would effectively vasodilate the pulmonary vasculature, improve hemodynamics, and treat a patient's elevated pulmonary blood pressure. As a result of the court's findings that the claims were not invalid but were infringed, the court stayed approval of Liquidia's NDA for Yutrepia until May 5, 2027, the expiration date of the '793 patent.

II. The '066 Patent

The '066 patent is directed to a pharmaceutical composition comprising treprostinil and a process of preparing a pharmaceutical product comprising treprostinil.

Asserted claim 1 of the '066 patent reads as follows:

> 1. A pharmaceutical composition comprising treprostinil or a pharmaceutically acceptable salt thereof, said composition prepared by a process comprising providing a starting batch of treprostinil having one or more impurities resulting from prior alkylation and hydrolysis steps, forming a salt of treprostinil by combining the starting batch and a base, isolating the treprostinil salt, and preparing a pharmaceutical composition comprising treprostinil or a pharmaceutically acceptable salt thereof from the isolated treprostinil salt, whereby a level of one or more impurities found in the starting batch of the treprostinil is lower in the pharmaceutical composition, and wherein said alkylation is alkylation of benzindene triol.

'066 patent at col. 17 ll. 51–63.

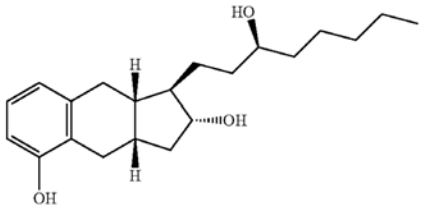
Asserted claim 6 of the '066 patent reads:

> 6. The pharmaceutical composition of claim 1, wherein the isolated salt is stored at ambient temperature.

Id. col. 18 ll. 34–35.

Asserted claim 8 of the '066 patent reads:

> 8. A process of preparing a pharmaceutical product comprising treprostinil or a pharmaceutically acceptable salt thereof, comprising alkylating a triol intermediate of the formula:



> hydrolyzing the resulting compound to form treprostinil, forming a salt of treprostinil stable at ambient temperature, storing the treprostinil salt at ambient temperature, and preparing a pharmaceutical product from the treprostinil salt after storage, wherein the pharmaceutical product comprises treprostinil or a pharmaceutically acceptable salt thereof.

Id. col. 18 ll. 38–61.

Additional asserted dependent claims are directed to crystalline forms (claim 2), a base selected from the group consisting of sodium, ammonia, potassium, calcium, ethanolamine, diethanolamine, N-methylglucamine, and choline (claim 3), and a pharmaceutical product prepared by the process recited in claim 8 (claim 9). *See id.* col. 17 ll. 64–67; col. 18 ll. 27–28, 62–63.

In the district court, United Therapeutics argued that Liquidia infringed claims 1–3, 6, 8, and 9 of the '066 patent. Liquidia responded that claims 1–3, 6, and 9 were invalid as anticipated by Moriarty[2] and that claims 1–3 and 6 were invalid as lacking written description support. Liquidia did not challenge the validity of claim 8, which is a chemical

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[2] R.M. Moriarty et al., *The Intramolecular Asymmetric Pauson-Khand Cyclization as a Novel and General Stereoselective Route to Benzindene Prostacyclins: Synthesis of UT-15 (Treprostinil)*, 69 J. ORGANIC CHEM. 1890 (2004).

process claim, in contrast to the other claims that are directed to compositions.

The district court found that United Therapeutics showed by a preponderance of the evidence that Liquidia's Yutrepia would infringe claims 1–3 of the '066 patent because Yutrepia met the impurities limitations of claim 1. But the court also found that claims 1–3, 6, and 9 were invalid as anticipated by Moriarty. Moriarty discloses the synthesis of analogues of benzindene prostacyclins, including treprostinil, which is designated in the publication as UT-15. Moriarty at 1890, 1892. The court also found that Liquidia showed by clear and convincing evidence that the claimed treprostinil product is functionally and structurally the same as the UT-15 treprostinil disclosed in Moriarty. The court thus concluded that claims 1–3 would have been infringed by Liquidia, but for the finding of anticipation, and that claims 6 and 9 were invalid as anticipated by Moriarty but not infringed by Liquidia.

In finding a lack of infringement of claim 6, the court construed the terms "ambient temperature" as room temperature (equal to or less than the range of 15°C to 30°C) and "stored"/"storing"/"storage" to have its plain and ordinary meaning. Using these constructions, the court determined that United Therapeutics failed to show by a preponderance of the evidence that Liquidia's Yutrepia production process stored treprostinil at ambient temperature, and therefore found that claims 6, 8, and 9 were not infringed. The court further found that any storage between steps of Liquidia's manufacturing process did not meet the limitations of claims 8 and 9, which require storage of treprostinil before preparing a pharmaceutical product.

The district court also found that the specification provided adequate written description support for the impurities limitation in claim 1, and that a skilled artisan would understand that the inventors were in possession of the

composition with the claimed impurities. The court thus concluded that Liquidia did not prove by clear and convincing evidence that claims 1–3 and 6 of the '066 patent were invalid for lack of written description.

In summary, the district court concluded that (1) claims 1, 4, and 6–8 of the '793 patent were not invalid and were infringed by Liquidia; (2) claims 1–3 of the '066 patent were invalid as anticipated by Moriarty and would have been infringed by Liquidia but for the finding of anticipation; (3) claims 6 and 9 of the '066 patent were invalid as anticipated by Moriarty and not infringed by Liquidia; and (4) claim 8 of the '066 patent was not invalid and not infringed by Liquidia. Liquidia appealed, and United Therapeutics cross-appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Liquidia raises five issues on appeal. First, Liquidia contends that the district court erred in construing the claim limitation "treating pulmonary hypertension" in claim 1 of the '793 patent not to include safety and efficacy. Second, Liquidia argues that the court erred in finding the asserted claims of the '793 patent enabled. Third, Liquidia contends that the court clearly erred in finding the asserted claims of the '793 patent supported by written description. Fourth, Liquidia contends that the court clearly erred in finding Liquidia liable for induced infringement of claims 1, 4, and 6–8 of the '793 patent. Fifth, Liquidia argues that the court clearly erred in finding claims 1–3 of the '066 patent to be infringed.

United Therapeutics raises two issues on cross-appeal. First, United Therapeutics asserts that the district court clearly erred in finding that Liquidia does not infringe claims 6 and 8 of the '066 patent. Second, United Therapeutics contends that the court clearly erred in finding that claims 1–3, 6, and 9 of the '066 patent are invalid as

anticipated by Moriarty. We address each appeal and cross-appeal argument in turn.

Infringement is a question of fact that we review, after a bench trial, for clear error. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017). A patent is directly infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a). "Whoever actively induces infringement of a patent shall be liable as an infringer." *Id.* § 271(b).

We review district court findings of anticipation under 35 U.S.C. § 102 and satisfaction of the written description requirement under 35 U.S.C. § 112 for clear error. *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019) (written description); *Forest Lab'ys, Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1268 (Fed. Cir. 2007) (anticipation). Enablement "is a question of law" that we review *de novo* after a bench trial. *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007). We review questions of claim construction *de novo* but review any underlying facts for clear error. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 991 (Fed. Cir. 1995); *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1328 (Fed. Cir. 2019).

I. The '793 Patent

A.

We first consider Liquidia's challenge to the district court's determination that the meaning of "treating pulmonary hypertension" does not require a showing of safety and efficacy. It asserts that a skilled artisan would understand the plain and ordinary meaning of "treating pulmonary hypertension" to encompass a method that accomplishes that goal safely and effectively. It asserts

that the parties' experts agreed that treatment with treprostinil, a vascular dilator, would not benefit Group 2 PH patients. It further asserts that while the specification of the '793 patent states that the treatment does not result in significant side effects, '793 patent at col. 5 ll. 16–20, and that administration of treprostinil is safe, *id.* col. 9 ll. 30–31, its expert testified that a skilled artisan would have concerns about administering inhaled treprostinil to Group 2 PH patients and that at least one earlier study, in which a treprostinil-like prostacyclin was administered to Group 2 PH patients, failed due to increased mortality.

United Therapeutics responds that the district court did not err in finding that the claimed administration of treprostinil would improve hemodynamics and hence treat a patient's elevated pulmonary blood pressure, including Group 2 PH patients. It asserts that Liquidia attempts to import limitations into the claims and that nothing in the specification requires the importation of safety and efficacy limitations into the claims. Finally, United Therapeutics asserts that while Liquidia's statements that a skilled artisan would have safety concerns in treating Group 2 PH patients with treprostinil may factor into Food and Drug Administration ("FDA") approval, they do not factor into claim interpretation.

As a threshold matter, we agree with the district court that "treating pulmonary hypertension" includes treating all five groups of pulmonary hypertension patients. The court did not err in finding that the specification encompasses all five groups when describing "pulmonary hypertension." In fact, the specification does not limit the scope of "pulmonary hypertension" to any particular subset of pulmonary hypertension patients. It refers to both "precapillary pulmonary hypertension" and "pulmonary hypertension," which, as the court found, demonstrates that the inventors view precapillary PH only as a subset of the broadly claimed "pulmonary hypertension." Thus, "treating pulmonary hypertension" includes treating all five

groups of pulmonary hypertension. *See* '793 patent at col. 9 ll. 36–37, col. 12 ll. 64–65, col. 16 ll. 64–65.

While the claims require "treating pulmonary hypertension comprising administering . . . a therapeutically effective single event dose of a formulation comprising treprostinil," *Decision*, at 467, the district court gave the phrase "therapeutically effective" a limiting construction. The district court held, and Liquidia does not challenge on appeal, that a person of ordinary skill in the art "would understand the plain and ordinary meaning of 'therapeutically effective single dose' to be a dose given in a single treatment session that causes an improvement in a patient's hemodynamics (reduced PAP or PVR)." *Id.* at 461; Appellee's Br. 39. We need not address whether the district court's construction was correct because Liquidia, on appeal, does not challenge that construction. Read in context, the claim language "treating pulmonary hypertension" does not import any additional efficacy limitations or any safety limitations.

Absent incorporation of safety and efficacy requirements in the claims, Liquidia's argument concerning the safety and efficacy of treating Group 2 PH patients is not before us. Questions of safety and efficacy in patent law have long fallen under the purview of the FDA. *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (noting that "the requirements under the law for obtaining a patent" are different from "the requirements for obtaining government approval to market a particular drug for human consumption"); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness . . . is more properly left to the [FDA]. Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings."); *In re Anthony*, 414 F.2d 1383, 1395 (CCPA 1969) ("Congress has given the responsibility to the FDA, not to the Patent Office, to determine in the first instance whether drugs are sufficiently safe for use that they can be introduced in the commercial

market . . . ."). We decline to insert the FDA's responsibilities into claims by importing requirements where they do not recite such limitations.

B.

We next turn to Liquidia's challenge to the district court's finding that the claims of the '793 patent are adequately enabled and supported by written description. Liquidia argues that the specification of the '793 patent provides no guidance or examples of treating Group 2 PH patients, and thus that a skilled artisan would have to engage in undue experimentation to practice the full scope of the claimed invention (*i.e.*, treating Group 2 PH patients).

Liquidia further argues that, even if the district court's construction of "treating pulmonary hypertension" as not requiring safety was proper, the claims of the '793 patent would still not be enabled because any changes in hemodynamics caused by inhalation of treprostinil would provide no benefit to Group 2 PH patients. Thus, a skilled artisan would not conclude that the '793 patent claims are enabled to the full scope of the claimed invention.

United Therapeutics responds that the district court did not err in concluding that Liquidia failed to show a lack of enablement. It contends that Liquidia failed to show by clear and convincing evidence that enablement would require undue experimentation with respect to Group 2 PH.

Further, even if the specification fails to describe how to treat Group 2 PH patients with treprostinil, United Therapeutics asserts, claims are not required to carve out all possible inoperative embodiments in a claim in order to avoid that claim being found not to be enabled. United Therapeutics asserts that if a skilled artisan has the information to limit the claims to operative embodiments, then the claims are not invalid. Here, United Therapeutics asserts, the skilled artisan has that information.

Liquidia also challenges the district court's finding that the claims are supported by an adequate written description. Liquidia argues that the '793 patent never describes treating Group 2 PH patients with inhaled treprostinil, but only Group 1, 3, and 4 patients, all of whom have precapillary PH. Thus, Liquidia contends, there is no information in the '793 patent specification sufficient for a skilled artisan to conclude that the inventors were in possession of a method of treating Group 2 PH patients with inhaled treprostinil.

Liquidia further argues that, even if the district court correctly construed "treating pulmonary hypertension" not to require a showing of safety, the claims still are not supported by written description because vasodilation of the pulmonary vasculature is not effective in treating Group 2 PH patients. Thus, Liquidia contends, a skilled artisan would have understood that the inventors did not invent or possess a method of treating Group 2 PH patients.

United Therapeutics responds that the district court did not clearly err in finding the claims of the '793 patent supported by an adequate written description. United Therapeutics argues that Liquidia's written description arguments fail for largely the same reasons as its enablement arguments. In particular, United Therapeutics asserts that the court did not err in holding that a skilled artisan would understand a therapeutically effective dose to be one that improves a patient's hemodynamics. United Therapeutics further contends that, although a physician may or may not decide to administer treprostinil to a Group 2 PH patient, that decision would be informed by FDA guidance, not the written description in the specification.

We agree with United Therapeutics that the claims are adequately enabled as they were construed by the district court. The specification of the '793 patent sufficiently enables the scope of the claims. *See, e.g.*, '793 patent at col. 7 ll. 7–67 (providing details on administration,

concentrations, and dosages of inhaled treprostinil for treating patients with pulmonary hypertension); *id.* col. 9 ll. 5–49 (describing an open label study upon acute safety, tolerability, and hemodynamic effects of inhaled treprostinil delivered over the course of a few seconds). While the court credited expert testimony concluding that a physician may have safety concerns in treating Group 2 PH patients with treprostinil and other vasodilators, *see Decision*, at 466–67, the court also found that the record demonstrates that the claimed administration of treprostinil vasodilates the pulmonary vasculature and reduces pulmonary blood pressure even in Group 2 PH patients, *id.* at 468. The court properly relied on expert testimony and record evidence to conclude that a skilled artisan would understand that the claimed administration of treprostinil would vasodilate the pulmonary vasculature, improve hemodynamics, and in this way for a single dose, treat a patient's elevated pulmonary blood pressure independent of the type (*i.e.*, group) of pulmonary hypertension patient. *Id.* That was all that the claims require under the district court's construction because, again, the parties do not dispute that a "therapeutically effective single event dose" is defined by "an improvement in a patient's hemodynamics (reduced PAP or PVP)." That a study—administering treprostinil-like prostacyclins to Group 2 PH patients—failed due to increased mortality, yet showed "improvement in a patient's hemodynamics," may be an issue for the FDA. But our focus is on the claimed invention. And on this record, with the district court's claim construction, the claims are adequately enabled.

We also agree with United Therapeutics that the district court did not clearly err in finding that the claims of the '793 patent are supported by an adequate written description. Written description requires that the specification reasonably convey to those skilled in the art that the inventor had possession of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d

1336, 1351 (Fed. Cir. 2010) (en banc). As the court noted, the '793 patent claims require "treating pulmonary hypertension comprising administering . . . a therapeutically effective single event dose of a formulation containing treprostinil," *Decision*, at 466–67, and the specification describes that. In other words, the specification shows possession for the claimed invention under the district court's construction.

Liquidia essentially asks us to treat Group 2 PH as a claimed species within a larger genus (*i.e.*, all five groups of pulmonary hypertension). But analogizing a subset of patients having a variant of a particular disease to traditional genus and species claims is inapt. It would be incorrect to fractionate a disease or condition that a method of treatment claim is directed to, and to require a separate disclosure in the specification for each individual variant of the condition (here, an individual group of pulmonary hypertension patients) in order to satisfy the enablement and written description provisions of 35 U.S.C. § 112, unless these variants are specified in the claims.

Again, because safety and efficacy are not recited in the claims, we need not deal with Liquidia's arguments. Disease-specific treatment requirements are matters for the FDA and medical practitioners. They are best suited to make these determinations because practitioners are informed by the findings of the regulatory agency to avoid treatment of patients who will not properly respond. And every claim to a method of treatment of an ailment has refinements. That is, for any given method of treatment claim, there may be a subset of patients who would not benefit from or should not take the claimed treatment. *See* Oral Arg. at 4:28–4:58, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-2217_05032023.mp3. That does not mean that such claims are not sufficiently enabled or supported by written description. A subset of unresponsive patients is not analogous to

unsupported species in a generic claim to chemical compounds.

C.

We next turn to Liquidia's challenge to the district court's finding that Liquidia was liable for induced infringement. Liquidia argues that it cannot be held liable for induced infringement because the '793 patent was found to be unpatentable in an IPR, and an unpatentable or invalid patent cannot be infringed. To support this assertion, Liquidia cites *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632, 644 (2015) (stating that if "an act that would have been . . . an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed"). Liquidia contends that *Commil* should be read as stating that knowledge of actual unpatentability determined in an IPR precludes having the necessary intent to induce infringement.

United Therapeutics responds that the Board's decision on the '793 patent is not final, and a non-final Board decision does not defeat Liquidia's liability for inducing infringement of the '793 patent. United Therapeutics contends that unpatentability is relevant to infringement liability only once a final adjudication of unpatentability or invalidity rules that there is no such patent to infringe.

We agree with United Therapeutics that the district court did not clearly err in finding that Liquidia induced infringement of the '793 patent. The court did not clearly err in finding that the label on Yutrepia, Liquidia's product, does not need to provide hemodynamic data to constitute inducement of infringement; it merely needs to instruct doctors and patients to administer a therapeutically effective single event dose, which it does. *Decision*, at 462–63. The court also did not clearly err in concluding that United Therapeutics proved that a single administration of Yutrepia will be therapeutically effective, as required by the claims of the '793 patent and constituting inducement.

Liquidia's reliance on *Commil*, 575 U.S. at 632, requires the '793 patent to have been invalidated, but as United Therapeutics argues, the corresponding IPR proceeding of the '793 patent is pending on appeal in this court. A pending, non-final litigation does not negate an intent to infringe that is otherwise supported by evidence. And we have previously held that an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights. *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018) ("[A]n affirmance of an invalidity finding, whether from a district court or the Board, has a collateral estoppel effect on all pending or co-pending actions."). Further, as the court noted, the Board's final written decision does not cancel claims; the claims are cancelled when the Director issues a certificate confirming unpatentability, which occurs only after "the time for appeal has expired or any appeal has terminated." 35 U.S.C. § 318(b). The '793 IPR decision thus has no impact here on a finding of induced infringement.

II. The '066 Patent

A.

We next turn to Liquidia's assertion on appeal that the district court clearly erred in finding that it infringed claims 1–3 of the '066 patent. Liquidia argues that United Therapeutics failed to meet its burden of proving infringement. In particular, Liquidia argues that United Therapeutics identified the starting batch as the treprostinil salt and the pharmaceutical composition as the bulk powder. Liquidia thus contends that a comparison between the impurities in the treprostinil salt and bulk powder would have been required to establish infringement of claims that require a lowering of impurities.

United Therapeutics responds that the district court did not clearly err in finding that Liquidia infringed claims 1–3 of the '066 patent. United Therapeutics contends that

the court based its conclusion on well-supported facts in finding that a skilled artisan would understand the relevant impurities to be those generated during the alkylation and hydrolysis steps used to create the starting batch of treprostinil.

We need not evaluate this argument that claims 1–3 of the '066 patent are not infringed, because Liquidia correctly argues that the district court did not clearly err in finding those claims invalid as anticipated by Moriarty. *See* Part II.B. Because unpatentable or invalid claims cannot be infringed, *Commil*, 575 U.S. at 644 ("To say that an invalid patent cannot be infringed . . . is in one sense a simple truth, both as a matter of logic and semantics."), the issue of infringement of claims 1–3 of the '066 patent has been rendered moot.

B.

Accordingly, we forthwith turn to United Therapeutics' argument on cross-appeal concerning the validity of claims 1–3. United Therapeutics argues that Moriarty does not teach the purification of treprostinil through salt formation and discloses no information on specific alkylation and hydrolysis impurities. United Therapeutics argues that it added the relevant impurities claim language to overcome validity challenges raised during prosecution, and the court failed to recognize the structural features that are imparted by the claimed salt-formation purification. United Therapeutics further contends that Moriarty discloses treprostinil with a purity of 99.7%, which does not establish that the product of Moriarty had the same level of alkylation or hydrolysis impurities of the claimed product.

Liquidia responds that the district court did not err in finding that claims 1–3, 6, and 9 of the '066 patent are anticipated by Moriarty. Liquidia argues that the claimed composition in Moriarty is the same as the claimed

composition in the '066 patent, and that United Therapeutics demonstrated no clear error in the court's findings.

We agree with Liquidia that the district court did not clearly err in finding that claims 1–3, 6, and 9 are invalid as anticipated by Moriarty. The claims of the '066 patent are directed to a pharmaceutical composition comprising, *inter alia*, treprostinil, prepared by alkylation and hydrolysis steps. It is thus referred to as a product-by-process claim. But a product-by-process claim is a product claim, even if claimed by a process by which it can be made. The claims also recite the presence of impurities.

We conclude that the district court did not clearly err in finding that these claims are anticipated by the Moriarty reference, which discloses treprostinil with impurities. The specification of the '066 patent discloses an impurity level of 99.7%–99.9%, '066 patent col. 14, table, whereas Moriarty similarly discloses the synthesis of impure treprostinil, designated in the publication as UT-15, having 99.7% purity, Moriarty at 1890, 1892, 1902. As these claims are product claims, they are anticipated by a disclosure of the same product irrespective of the processes by which they are made. Further, United Therapeutics did not provide any expert or fact witness rebutting Liquidia's expert's opinions or providing testimony identifying any structural or functional differences between the Moriarty treprostinil and the claimed treprostinil. *Decision*, at 456. The court thus did not err in finding that claims 1–3, 6, and 9 of the '066 patent are anticipated by Moriarty.

C.

United Therapeutics also argues on cross-appeal that the district court clearly erred in finding that Liquidia does not infringe claims 6 and 8 of the '066 patent. United Therapeutics contends that claims 6 and 8 require that the treprostinil salt be stored at ambient temperature, and that Liquidia stores treprostinil salt at ambient temperature during production, thus infringing the claims. United

Therapeutics contends that Liquidia's promise not to make its product with batches of treprostinil salt that were stored at ambient temperature is insufficient to avoid a finding of infringement.

United Therapeutics also contends that the district court erred in construing the term "storage" in claims 6 and 8 as excluding storage during manufacturing but including storage during shipment of the product. United Therapeutics further contends that Liquidia also infringes claim 8 through ambient storage that occurs after the composition recited in claims 1–6 is prepared and before the drug product of claim 8 is prepared.

Liquidia responds that the district court did not clearly err in finding that it does not infringe claims 6 and 8 of the '066 patent. In particular, Liquidia notes that the court based its findings of non-infringement on several clear findings of fact, including that (1) Liquidia's NDA requires the treprostinil salt to be stored at a temperature of 2–8°C; (2) Liquidia asserted that it would not use treprostinil salt batches that have been stored at ambient temperature; and (3) Liquidia begins preparing a pharmaceutical product during step 1 of its production process. Liquidia further asserts that the NDA storage specifications are regulatory requirements, not mere recommendations or promises.

Liquidia further responds that the district court did not err in its construction of the term "storage." Liquidia asserts that United Therapeutics mischaracterizes Liquidia's production process, and that its production process is a single production process, not two stages separated by a period of ambient storage.

We agree with Liquidia that the district court did not clearly err in finding that it does not infringe claims 6 and 8 of the '066 patent. The court credited Liquidia's representations to the FDA that it would store treprostinil sodium between 2°C and 8°C. The court also found that United Therapeutics provided no evidence showing that

Liquidia used ambient-temperature-stored batches of treprostinil in its manufacturing process in making a pharmaceutical composition as required by claim 6 or claim 8. Without a showing that Liquidia stores treprostinil at ambient temperature, there can be no infringement of the claims.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, the decision of the United States District Court for the District of Delaware is affirmed.

AFFIRMED

COSTS

No costs.